

WE CLAIM:

1. An implantable medical device that provides a valve for regulating fluid flow through a body vessel, comprising:

5 a support frame having radially compressed and radially expanded configurations; and

at least one leaflet having first and second edges and being moveable between a first position that permits said fluid flow in a first direction and a second position that substantially prevents said fluid flow in a second, opposite direction, the first edge attached to the support frame and the second edge being free of the support frame;

10 wherein a portion of the support frame and the second edge of the at least one leaflet cooperatively define an opening that permits a controlled amount of fluid flow in the second, opposite direction.

15 2. The implantable medical device according to claim 1, wherein the support frame is a self-expandable support frame.

3. The implantable medical device according to claim 2, wherein the support frame is formed of a nickel-titanium alloy.

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4. The implantable medical device according to claim 1, wherein the at least one leaflet is formed of a bioremodellable material.

25 5. The implantable medical device according to claim 4, wherein the bioremodellable material comprises an extracellular matrix material.

6. The implantable medical device according to claim 4, wherein the bioremodellable material comprises small intestine submucosa.

7. The implantable medical device according to claim 1, further comprising at least one suture attaching the first edge of the at least one leaflet to the support frame.

5 8. The implantable medical device according to claim 1, wherein the at least one leaflet comprises first and second leaflets.

9. The implantable medical device according to claim 1, wherein the total open area of the opening is less than the cross-sectional area of said body
10 vessel at a desired point of treatment in said body vessel.

10. The implantable medical device according to claim 1, wherein the total open area of the opening is less than about 50% of the cross-sectional area of said body vessel at a desired point of treatment in said body vessel.

15 11. The implantable medical device according to claim 1, wherein the total open area of the opening is less than about 25% of the cross-sectional area of said body vessel at a desired point of treatment.

20 12. The implantable medical device according to claim 1, further comprising a moveable flap adjacent the opening and adapted to temporarily and substantially close the opening.

25 13. An implantable medical device that provides a valve for regulating fluid flow through a body vessel comprising:

an expandable support frame; and

at least one leaflet attached to the support frame, the at least one leaflet being formed of a bioremodellable material and moveable between a first position that permits said fluid flow in a first direction and a second
30 position that substantially prevents said fluid flow in a second, opposite direction;

wherein the support frame and the at least one leaflet cooperatively define an opening that permits a controlled amount of fluid flow in the second, opposite direction.

5 14. The implantable medical device according to claim 13, wherein the bioremodellable material comprises an extracellular matrix material.

 15. The implantable medical device according to claim 13, wherein the bioremodellable material comprises small intestine submucosa.

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 16. The implantable medical device according to claim 13, further comprising a moveable flap adjacent the opening and adapted to temporarily and substantially close the opening.

15 17. An implantable medical device that provides a valve for regulating fluid flow through a body vessel, comprising;

 an expandable support frame; and

 at least one leaflet attached to the support frame, the at least one leaflet being formed of a bioremodellable material and movable between
20 a first position that permits said fluid flow in a first direction and a second position that substantially prevents said fluid flow in a second, opposite direction, the at least one leaflet defining an opening that permits a controlled amount of fluid flow in the second, opposite direction.

25 18. The implantable medical device according to claim 17, wherein the bioremodellable material comprises an extracellular matrix material.

 19. The implantable medical device according to claim 17, wherein the bioremodellable material comprises small intestine submucosa.

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20. The implantable medical device according to claim 17, wherein the opening is substantially square, substantially triangular, substantially ovoid, or teardrop-shaped.

5 21. The implantable medical device according to claim 17, further comprising a moveable flap adjacent the opening and adapted to temporarily and substantially close the opening.

22. An implantable medical device that provides a valve for regulating
10 fluid flow through a body vessel, comprising;
an expandable support frame;
a first leaflet formed of a bioremodellable material and having first and second edges, the first edge attached to the support frame, the first leaflet defining a first opening; and
15 a second leaflet formed of a bioremodellable material and having third and fourth edges, the third edge attached to the support frame and the fourth edge cooperating with the second edge of the first leaflet to define a valve aperture having open and closed configurations, the second leaflet defining a second opening;
20 wherein the first and second openings permit a controlled amount of fluid flow through said medical device when the valve aperture is in the closed configuration.

23. The implantable medical device according to claim 22, wherein
25 the bioremodellable material comprises an extracellular matrix material.

24. The implantable medical device according to claim 22, wherein the bioremodellable material comprises small intestine submucosa.

25. An implantable medical device that provides a valve for regulating fluid flow through a body vessel, comprising:

a support frame;

5 at least one leaflet attached to the support frame and being moveable between a first position that permits said fluid flow in a first direction and a second position that substantially prevents said fluid flow in a second, opposite direction, the leaflet defining an opening that permits a controlled amount of fluid flow in the second, opposite direction; and

10 a moveable flap adjacent the opening and adapted to temporarily and substantially close the opening.

26. The implantable medical device according to claim 25, wherein the at least one leaflet is formed of a bioremodellable material.

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27. The implantable medical device according to claim 26, wherein the bioremodellable material comprises an extracellular matrix material.

28. The implantable medical device according to claim 26, wherein
20 the bioremodellable material comprises small intestine submucosa.